Washington, D.C. 20250

OCT 9 2003

Dr. Birgitte Povlsen, Head Senior Veterinary Officer Director Food Control Department Danish Veterinary and Food Administration Moerkhoel Bygad 19 DK – 2860 Soeborg DENMARK

Dear Dr. Povlsen:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) audit of Denmark's meat inspection system conducted from January 9, 2003 through February 11, 2003. Comments by Denmark on the draft final audit report have been included as Attachment "G" in the final audit report.

If you have any questions or need additional information, please contact me by telephone at (202) 720-3781. You may also contact me by fax at (202) 690-4040 or by e-mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen, Director

International Equivalence Staff

Sally Stratmoung D

Office of International Affairs

Enclosure

#### CC

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Country File (Denmark FY 2003 Audit)

# **FINAL**

SEP - 8 2003

# FINAL REPORT OF AN AUDIT CARRIED OUT IN DENMARK COVERING DENMARK'S MEAT AND POULTRY AND EGG PRODUCTS INSPECTION SYSTEM

January 9 through February 11, 2003

Food Safety and Inspection Service United States Department of Agriculture

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# ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA Central Competent Authority (Danish Veterinary Food

Administration)

E. coli Escherichia coli

FSIS Food Safety and Inspection Service

PR/HACCP Pathogen Reduction / Hazard Analysis and Critical Control Point

Salmonella Salmonella species

SSOP Sanitation Standard Operating Procedures

VEA European Community/United States Veterinary Equivalence

Agreement

#### 1. INTRODUCTION

The audit took place in Denmark from January 9 to February 11, 2003.

An opening meeting was held on January 9, 2003 in Copenhagen with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of the Danish meat inspection system. General information about the Danish Veterinary Food Administration, animal disease status and itinerary were provided to the auditor.

The auditor was accompanied during the entire audit by representatives from the CCA, the Danish Veterinary Food Agency, and representatives from the regional and local inspection offices.

#### 2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three regional inspection offices, two laboratories performing analytical testing on United States-destined product, two cattle and two swine slaughter establishments, six cold stores and three meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	3	Interviewed 3 chief Vets.
Laboratories		2	
Meat Slaughter Establishments		4	
Meat Processing Establishments		3	
Cold Storage Facilities		6	

#### 3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to 13 establishments: four slaughter establishments, three processing establishments and six cold storage facilities. The third part involved visits to one government and one private laboratory. The Food Region

Northern Jutland Microbiology Laboratory was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species. The Food Region Ringsted Residue Laboratory was conducting analyses of field samples for Denmark's national residue control program.

Program effectiveness determinations of Denmark's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. Denmark's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Denmark and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Denmark under provisions of the Sanitary/Phytosanitary Agreement. For *E. coli* and *Salmonella* equivalence determination see Sections 11.3 and 13.2 respectively.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists"

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

The last two audits of Denmark inspection system have shown serious problems.

Of the problems identified in April 2001, the following had been corrected by the audit in February 2002:

- Pre-shipment document reviews had not been developed and implemented in 10 of 25 establishments. *This had been resolved*.
- Additional sanitizers were required in essential locations in two of nine establishments.

This had been resolved.

• Condensation controls were inadequate in two establishments. *This had been resolved*.

Of the problems identified in April 2001, the following had not been corrected by the February 2002 audit:

- Maintenance and cleaning of over-product equipment had been neglected in four of the nine establishments visited. Similar problems were found in four of the 11 establishments.
- Light was inadequate in the retained carcass inspection areas in two establishments. Light was again found to be inadequate in two establishments.
- Documentation of Sanitation Standard Operating Procedures was inadequate in two establishments. Problems were again identified, but in only one establishment.

The following additional concerns were identified during the February 2002 audit:

• Visible fecal contamination was found on product that had passed all establishment and DVFA inspection controls in two of the 11 establishments audited on-site. Also,

in these two establishments, the written controls for enforcement of the zero-tolerance policy for visible fecal contamination were not followed as required.

- During the year prior to this audit, supervisory internal reviews were not consistently conducted monthly.
- Inadequate cleaning of product-contact equipment before use was found in three of the seven establishments in which exposed product was handled.

#### 6. MAIN FINDINGS

#### 6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Denmark legislation.

#### 6.2 Government Oversight

#### 6.2.1 CCA Control Systems

The Danish Ministry for Food, Agriculture, and Fisheries was divided into four departments, including the Food and Environment Department (FED). Within FED was the Veterinary and Foodstuffs section, which contained the Danish Veterinary and Food Administration. Within DVFA were the Danish Veterinary Service, the Food Control Department Administration, and the Danish Veterinary Laboratory/Institute. Also within DVFA, and directly under the control of the Director General for DVFA, were the 11 Regional Veterinary and Food Control Authorities (RVFCAs). In general, the 11 Regional Authorities had the same four departments. Within the Food Control Department of each RVFCA were the Chief Veterinarians, who served as field supervisors over the resident veterinarians and inspectors within one or more certified establishments.

#### 6.2.2. Ultimate Control and Supervision

The CCA must have ultimate control and supervision over official activities of all employees and certified establishments.

- One establishment was decertified during this audit.
- Two establishments required a 30-day notice from the CCA.

#### 6.2.3 Assignment of Competent, Qualified Inspectors

The CCA must ensure the assignment of competent and qualified inspectors.

• Supervision of inspectors in the certified establishments needs to be improved. At three establishments there were deficiencies in inspection controls.

• The EC Directive 64/433 implementation deficiencies were observed in the categories of establishment grounds and pest control, establishment construction/maintenance, light, ventilation, plumbing and sewage, dressing and room/lavatories, equipment and utensils, sanitary operations, and employee hygiene.

#### 6.2.4. Authority and Responsibility to Enforce the Laws

The CCA must have authority and responsibility to enforce U.S. requirements and must exercise that authority.

• In one establishment, zero tolerance for fecal contamination was not enforced.

#### 6.2.5 Adequate Administrative and Technical Support

The CCA must have adequate administrative and technical support to operate the country's inspection system.

• No problems were observed.

#### 6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the regional office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

#### 6.3.1 Audit of Regional and Local Inspection Sites

No concerns arose as a result of the audit of Regional and Local Inspection offices. There was proper level of oversight under; management structure, independence and resources, recruitment and training, prioritization of controls and documentation of controls.

#### 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments—four slaughter establishments, three processing establishments, and six cold storage facilities. One establishment was delisted by Danish Veterinary Food Administration because of zero-tolerance violation for fecal contamination, improper *E. coli* testing documentation and HACCP deficiencies. Two establishments received "30-day notices" (notification in writing that corrective actions must be implemented within 30 days) from Denmark because of SSOP, Sanitation, and HACCP deficiencies. These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted on the attached individual establishment reports.

#### 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

The Government Food Region Ringsted Residue Laboratory was audited on January 24, 2003. The Government Food Region Northern Jutland Microbiology Laboratory was audited on January 21, 2003.

The findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), Section 12 (RESIDUE CONTROLS), OR Section 13.2 (Testing for *Salmonella* species) of this report.

#### 9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviews is Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Denmark's inspection system had controls in place for product storage practices.

In addition, and except as noted below, Denmark's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, welfare facilities, and outside premises.

The following deficiencies were observed:

- establishment grounds and pest control
- establishment construction/maintenance
- light
- ventilation
- plumbing and sewage
- dressing room/lavatories
- equipment and utensils
- sanitary operations
- employee hygiene

#### 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP program in the eight establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies:

- implementation of SSOP
- maintenance and evaluation of the effectiveness of SSOP
- corrective action and daily records

#### 9.2 EC Directive 64/433

In six establishments, the provisions of EC Directive 64/433 were effectively implemented. In the seven establishments with deficiencies, the specific deficiencies are noted in the applicable sections and sub-sections of this report and in the attached individual establishment checklists.

#### 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviews is Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that the Danish inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

#### 11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

#### 11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

#### 11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the seven establishments. Four establishments had adequately implemented the PR/HACCP requirements.

• Three establishments had HACCP implementation deficiencies; one of them had repeat deficiencies. The inspection officials took corrective action. In one of these three establishments, the basic HACCP requirements were not met.

Deficiencies observed in three establishments included:

- critical limits
- monitoring activities
- corrective action and verification

These categories were not properly described in one establishment under basic requirements. Monitoring, corrective action and verification were not implemented.

#### 11.3 Testing for Generic E. coli

Denmark has adopted the FSIS regulatory requirements for generic E. coli testing with the exception of the following different equivalent requirements:

#### 1. Sampling tools.

- Denmark uses a gauze swab sampling tool. The gauze swab is a generally/internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.
- The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.
- The sampling tool does not contaminate the surface of the carcass.
- 2. Analytical methods (Different methods).
  - Denmark uses an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.
  - The method is approved by the AOAC International or an internationally recognized scientific organization.

Four of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in three of the four slaughter establishments.

• In one establishment a statistical process control to evaluate the results of testing for generic *E. coli* had still not been properly implemented and documented.

#### 11.4 Testing for *Listeria Monocytogenes*

Testing for *Listeria monocytogenes* is performed where required.

#### 11.5 EC Directive 64/433

In six establishments, the provisions of EC Directive 64/433 were effectively implemented.

#### 11.6 Ante and Post Mortem Inspection

- Unified synchronization of inspected carcasses needs improvement in one establishment
- Extremely dirty animals received on ante-mortem inspection

#### 12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews is Residue Controls. At the government residue laboratory that was audited, sample procedures, analytical procedures, and Quality Assurance procedures were evaluated. These procedures covered areas of sample handling, sampling frequency, timely analyses, compositing procedures, interpretation of compositing data, data reporting, acceptable method, correct tissues, equipment operation, instrument printouts, minimum detection level, recovery frequency, percent recovery, check sample frequency, analysts with check samples, corrective actions and international check samples.

The Government Food Region Ringsted Residue Laboratory was visited on January 24, 2003. No deficiencies were noted.

Denmark's National Residue Control Program for 2003 was being followed and was on schedule.

12.1 FSIS Requirements were being followed.

#### 12.2 EC Directive 96/22

In the Food Region Ringsted Residue Laboratory, the provisions of EC Directive 96/22 were effectively implemented

#### 12.3 EC Directive 96/23

In the Food Region Ringsted Residue Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

#### 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

#### 13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

#### 13.2 Testing for Salmonella

Denmark has adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing is the same with exception of the following equivalence measures:

1. Sample collector: Establishments take samples.

- The government of Denmark provides a clearly written sampling plan with instruction for sample collection and processing that is followed by all applicable export establishments.
- All applicable veterinarians are properly and uniformly trained. The veterinarians train the establishment employees. The trained veterinarian will observe the collection/storage/transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed once every week by the DVFA where the official veterinarian collects samples and the DVFA analyzes the sample.
- The government of Denmark uses the test results to monitor establishment performance over time.
- The government of Denmark takes immediate action any time an establishment fails to meet a *Salmonella* performance standard.
- 2. Laboratories. Private laboratories analyze samples.
  - The laboratories are independent non-government or establishment laboratories that are all accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyzes are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.
  - All accredited laboratories have a formal program to ensure that lab personnel are properly trained, that there are suitable facilities and equipment, that there is a written quality assurance program, and that there are adequate reporting and record keeping facilities.
  - Test results are provided directly to the government veterinarian.

#### 3. Salmonella testing strategy

- Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.
- Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.

- Denmark's testing program has statistical criteria for evaluating test results.
- The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

#### 3. Sampling tools.

- The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.
- The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.
- The sampling tool does not contaminate the surfaces of the carcass.

Four of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic program. Testing for *Salmonella* species was properly conducted in all four establishments.

#### 13.3 Species Verification

At the time of this audit, Denmark was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

#### 13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

#### 13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

No livestock or meat was imported from third countries for product eligible for export to the United States.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

#### 14. CLOSING MEETING

A closing meeting was held on February 11, 2003 in Copenhagen with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

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The CCA understood and accepted the findings.

Dr. Oto Urban

International Audit Staff Officer

# 15. ATTACHMENTS

Individual Foreign Establishment Audit Forms Laboratory Review Reports Foreign Country Response to Draft Final Audit Report

0.3. 0.544,977/55/7 (0.5.4.54.0), 0.7.45 50.00 (0.4557), 4.00 (0.05507) 0.0.554, 0.0.5 FEMENICATE NAME OF FORE BY LABORATORS 1-21-03 Government Food Region Northern Judand FOREIGN COUNTRY LABORATORY REVIEW Laboratory FOREIGN GOV'T AGENCY CITY & COUNTRY ADDRESS OF LABORATORY Danish Veterinary and Food Aalborg, Denmark Sofiendalsvej 90, 9200 Aalborg SV Administration NAME OF REVIEWER NAME OF FOREIGN OFFICIAL Dr. Oto Urban Dr. Ole A. Kyvsgard Residue Code/Name E.co Sal REVIEW ITEMS ITEM # Sample Handling 01 A A SAMPLING PROCEDURES Sampling Frequency 02 EVALUATION CODE A A Timely Analyses 03 A A Compositing Procedure 04 0 O Interpret Comp Data 05 0 0 Data Reporting 06 A A Acceptable Method 07 CODE A A ANALYTICAL PROCEDURES Correct Tissue(s) 80 NOL A A Equipment Operation 09 0 0 Instrument Printouts 10 0 o Minimum Detection Levels 11 o o QUALITY ASSURANCE Recovery Frequency 12 o O CODE PROCEDURES Percent Recovery 13 0 O EVALUATION Check Sample Frequency 14 A A All analyst w/Check Samples 15 A A Corrective Actions 16 A Á International Check Samples 17 Á Ä PROCEDURES CODE REVIEW Corrected Prior Deficiencies 18 O 0 EVAL. 19 SIGNATURE OF REVIEWER DATE 1/5/1/2

FOR	EIGN COUNTRY LAE	BORATORY REVIEW	PEVLEW DATE	NAME OF FORE BY LABORATORY	
	(Comment S		1-21-03	Government Food Region Northern Juda Laboratory	
FOREIGN GO Danish Vet Administra	OV'T AGENCY CITY & C terinary and Food Aalborg,		γ ark	ADDRESS OF LABORATORY Sofiendalsvej 90, 9200 Aalborg SV	
NAME OF R Dr. Oto Ui		NAME OF FOREIG Dr. Ole A. Kyv			
RESIDUE	ITEM		COMM	ENTS	

U.S. DEPARTMENT OF AGRICULTURE DO GARETY AND WARROTICK SERVICE BENGEN DATE NAME OF FORE BY LABORATORY NTERNATIONAL PROGRAMS 1-24-63 Government Food Region Ringsted Residue FOREIGN COUNTRY LABORATORY REVIEW Laboratory FOREIGN GOV'T AGENCY CITY & COUNTRY ADDRESS OF LABORATORY Danish Veterinary and Food Ringssted, Denmark Sondervang 4. DK-4100 Ringsted Administration NAME OF REVIEWER NAME OF FOREIGN OFFICIAL Dr. Oto Urban Dr. Arne Kongsted, M.Sc Inga Orntoft 111 200 203 300 400 500 800 SP Residue Code/Name 100 REVIEW ITEMS ITEM # Sample Handling 01  $\mathbf{A}$ A Å A Á A A A A SAMPLING PROCEDURES Sampling Frequency 02 EVALUATION CODE A A A A A A A A A Timely Analyses 03 A A A Α A A A A A Compositing Procedure 04 o 0 O 0 0 0 0 0 0 Interpret Comp Data 05  $\mathbf{o}$ 0 O o  $\mathbf{o}$ o O 0  $\mathbf{o}$ Data Reporting 06 A A A A A A A Á A Acceptable Method 07 CODE A A A  $\mathbf{A}$ A A A  $\mathbf{A}$  $\mathbf{A}$ ANALYTICAL PROCEDURES Correct Tissue(s) 08 EVALUATION A A A  $\mathbf{A}$ A A A A Á Equipment Operation. 09 A A A A A A A A A Instrument Printouts 10 A A A Á A A A Minimum Detection Levels 11 o A A A A A Á A A QUALITY ASSURANCE Recovery Frequency 12 O  $\mathbf{A}$ A  $\mathbf{A}$ A A A A A CODE PROCEDURES Percent Recovery 13  $\mathbf{A}$ A A A A A A A 0 EVALUATION Check Sample Frequency 14 A A A  $\mathbf{A}$ Á Á A A A All analyst w/Check Samples 15 A A A A  $\mathbf{A}$ A A A A Corrective Actions 16  $\mathbf{A}$ A A A Α A Á A A International Check Samples 17 A A A A Á A A Á A PROCEDURES CODE 18  $\mathbf{o}$ Corrected Prior Deficiencies 0 0 0 0 0 0 O 0 EVAL. CODE 19 OTHER REVIEW EVAL 20

Mn.

DATE

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SIGNATURE OF REVIEWER

FOR	EIGN COL	INTRY LABORATO	RY REVIEW	SELEW DATE	TWAME OF FOREIGN	: LABORATORY	
		Comment Sheet)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1-24-03	Government Food Laboratory	i Region Ringsted Residue	
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NAME OF R		-	l .	FOREIGN OFFICIAL Kongsted, M.Sc Inga Orntoft			
RESIDUE	ITEM			COMM	ENTS		
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#### United States Department of Agriculture Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

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Part A - Sanitation Standard Operating Procedures			llai	Part D - Continued		
Basic Requirements	(000)	Audit Results		Economic Sampling	Audit Result	
7. Written SSOP		İ	33	Scheduled Sampie		
8. Records documenting implementation.	1111		34	. Species Testing	0	
9. Signed and dated SSOP, by on-site or overall authority.			35	Residue		
Sanitation Standard Operating Procedures (SSOF	2)			Part E - Other Requirements		
Ongoing Requirements  10. Implementation of SSOP's, including monitoring of implem	entation	X	36	Export		
11. Maintenance and evaluation of the effectiveness of SSOP's	***************************************	X	₽	Import	1	
Corrective action when the SSOPs have failed to prevent oppoduct contamination or adulteration.				Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39	Establishment Construction/Maintenance	X	
Part B - Hazard Analysis and Critical Control			40.	Light		
Point (HACCP) Systems - Basic Requirements				Ventilation		
14. Developed and implemented a written HACCP plan.			41.	vermation		
<ol> <li>Cortents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective a</li> </ol>	ations.		-	Plumbing and Sewage		
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	e			Water Supply  Dressing Rooms/Lavatories		
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>				Equipment and Utensils	X	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46.	Sanitary Operations	X	
18. Monitoring of HACCP plan.			47.	Employee Hygiene		
19. Verification and validation of HACCP plan.		X	10	Condemned Product Control		
20. Corrective action written in HACCP plan.				Condition roddst Control		
21. Reassessed adequacy of the HACCP plan.				Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur	of the urrences.		49.	Government Staffing		
Part C - Economic / Wholesomeness			50.	Daily Inspection Coverage		
23. Labeling - Product Standards		0	51.	Enforcement	<del>-  </del>	
24. Labeling - Net Weights		0				
25. General Labeling		0	52.	Humane Handling		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	isture)	0	53.	Animal Identification	i	
Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem Inspection		
27. Written Procedures			 55.	Post Mortem Inspection		
28. Sample Collection/Analysis				·		
29. Records				Part G - Other Regulatory Oversight Requirements		
Salmonella Performance Standards - Basic Requir	ements	5	6. E	European Community Directives	Х	
30. Corrective Actions	· · · · · · · · · · · · · · · · · · ·	5	57. 1	Monthly Review	ļ	
11. Reassessment		5	58.		1 2	
2. Written Assurance	:	5	9.			

#### 60. Observation of the Estab ishment

DENMARK - Est. 13 1-16-03

- 10/46. Condensation was observed over a conveyor belt in the boning room. The establishment took immediate corrective action.
- 46/56 Plastic containers designated for edible purposes were used for inedible product. DVFA ordered immediate corrective action.
- 10/45/56 Inadequately cleaned knives and large plastic containers were observed before the start of operations in production areas. This was corrected by the establishment officials before operations were allowed to begin. This was in violation of EC Directive 64/433.
- 11/39/56 Flaking paint and rust was observed on rails in product traffic areas in the boning room. This was scheduled for correction by the establishment officials.
- 10/11. Grease from rails was observed on several carcasses. DVFA ordered immediate corrective action.
- 11/39/56 Rusty rails and flaking paint was observed over the product in one of the trimming coolers; corrective actions by the establishment officials were not immediate.
- 19. No verification of the monitoring of critical limits was performed.

The DVFA officials A Notice of Intent to Delist if the deficiencies identified were not addressed and corrected within 30 days.

62. AUDÎTOR SIGNATURE AND DATE

#### United States Department of Agriculture Food Safety and Inspection Service

# Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAMERING LOCATION	2 AUDITICATE	S ESTABLISHMENTING 4, NAME OF COU	NTEY
Danish Crown	01 - 29 - 03	14 Denmark	
Langbro 7. Blans	5, NAME OF AUDIT	DR(S) 6. TYPE OF AUD	
6400 Sonderborg	Dr. Oto Urba	n X ON-SITE AU	DIT DOCUMENT AUDIT
Place an X in the Audit Results block to inc	dicate noncomp	liance with requirements. Use O	f not applicable.
Part A - Sanitation Standard Operating Procedures ( Basic Requirements	SSOP) Audit Results	Part D - Continued Economic Sampling	/ tout
7. Written SSOP		33. Scheduled Sample	0
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirem	ents
10. Implementation of SSOP's, including monitoring of implemen	ntation.	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
<ol> <li>Corrective action when the SSOPs have failed to prevent dir product contamination or adulteration.</li> </ol>	ect	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
<ol> <li>Contents of the HACCP list the fcod safety hazards, critical control points, critical limits, procedures, corrective act</li> </ol>	ions.	42. Plumbing and Sewage	
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rcoms/Lavatories  45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.		47. Employee Hygiene	
19. Verification and validation of HACCP plan.	X	48. Condemned Product Control	
20. Corrective action written in HACCP plan.		Dart E. Increation Dequir	omonts
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Require	affents
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0	52. Humane Handling	
25. General Labeling	0	oz. Hamane Hamanig	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mois	ture) O	53. Animal Identification	
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	
27. Written Procedures		55. Post Mortem Inspection	
28. Sample Collection/Analysis			
29. Records		Part G - Other Regulatory Oversight F	Requirements
20. 1000,00		56. Euroœan Community Directives	
Salmonella Performance Standards - Basic Require	ments		
30. Corrective Actions		57. Monthly Review	
31. Reassessment		58.	
82 Written Assurance		59.	

#### 60. Observation of the Establishment

DENMARK - Est. 14 1-29-03

- 11 Pieces of meat scraps and fat were found on product-contact equipment (meat hangers and conveyor belts) before the start of operations. The establishment officials took corrective actions.
- 19 Critical limits were monitored as required, but the verification procedures were not adequately performed. DVFA ordered prompt correction.

OR 62. AUDITOR SIGNATURE A

61. NAME OF AUDITOR

Dr. Oto Urban

11/1/19/03

#### United States Department of Agriculture Food Safety and Inspection Service

# Foreign Establishment Audit Checklist

nu ESTABLISHMENT NAME AND LODATION	2. AUC TIDATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY	
Arhus Slaugtehus A/S 61 = :		34 Denmark	
Jaegergardsgade 152-154	5 NAME OF AUG	DITOR(S) 6. TYPE OF AUDIT	
8000 Arhus C			
	Dr. Oto Url		ICUA T/JEMI
		npliance with requirements. Use O if not applicat	ole.
Part A - Sanitation Standard Operating Procedures ( Basic Requirements	SSOP) Aud Resu	· ·	Audit Results
7. Written SSOP		33. Scheduled Sample	_
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP)		Part E - Other Requirements	
Ongoing Requirements  10. Implementation of SSOP's, including monitoring of implement	totion 7.	36. Export	
Maintenance and evaluation of the effectiveness of SSOP's.	ntation. X	37. Import	
12. Corrective action when the SSOPs have failed to prevent dir	ect		
product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective act</li> </ol>	ions. X	42. Plumbing and Sewage	X
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>		43. Water Supply	
The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories  45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	X
18. Monitoring of HACCP plan.	X	47. Employee Hygiene	
19. Verification and validation of HACCP plan.	X		
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	^	Part F - Inspection Requirements	
Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occurr		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards			
24. Labeling - Net Weights	0	51. Enforcement	X
25. General Labeling	0	52. Humane Handling	
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moist		53. Animal Identification	
Part D - Sampling			
Generic E. coli Testing		54. Ante Mortem Inspection	X
7. Written Procedures	X	55. Post Mortem Inspection	X
8. Sample Collection/Analysis			
9. Records		Part G - Other Regulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requirer	ments	56. European Community Directives	X
O. Corrective Actions		57. Monthly Review	
1. Reassessment		58.	
2 Written Assurance		59.	

#### 60. Observation of the Establishment

#### DENMARK Est. 34 1-23-03

- 10/46. Condensation was observed over exposed product and exposed product traffic areas (receiving room, cooler). This was corrected by the establishment officials.
- 15. Many critical limits were not defined in the written HACCP plan (basic non-compliance with HACCP requirements).
- 15/20. The description of corrective actions, to be taken in the event that critical limits are exceeded, was inadequate (basic non-compliance with HACCP requirements). Inadequate development of the HACCP program was one of the deficiencies identified during the previous FSIS audit of this establishment.
- 19. No verification of the monitoring of critical limits was written in the HACCP plan or performed (basic and implementation non-compliance with HACCP requirements).
- 18. Fecal contamination was observed on a carcass in a cooler and on tails that passed final inspection and had been removed. Fecal contamination on product that had passed final inspection was a repeat finding from the previous FSIS audit of this establishment. These deficiencies were corrected after the auditor pointed them out.
- 27. A statistical process control to evaluate the results of testing for generic *E. coli* had still not been properly implemented and documented (this was a repeat finding).
- 40. Light was inadequate in the suspect pen.
- 41/42. A foul sewer odor was coming from a drain in the shipping room. The auditor was told that it was expected to be corrected after April 2003.
- 46/56 Beef carcasses were contacting the boot guard of the eviscerator's platform; the platform was not being sanitized after the contact. The eviscerator was frequently observed to stand on the boot guard, adding to the contamination. This did not meet the requirements of EC Directive 64/433. Similar common-contact was one of the deficiencies identified during the previous FSIS audit of this establishment. DVFA officials ordered correction.
- 46/56 Dirty hooks were observed in the product receiving room and there was not enough water in the sterilizer in the reinspection room. This did not meet the requirements of EC Directive 64/433. These deficiencies were corrected immediately by the company officials.
- 46/54 The animals presented for slaughter were extremely dirty, with large clumps of dry feces and straw attached to their hides, contributing to the sanitary dressing problems.
- 55. Some large bruises that had not been trimmed were observed on carcasses in the cooler.

Note: This establishment had been found unacceptable during the previous FSIS audit on February 18, 2002, and had been recently re-listed on the basis of assurances provided to FSIS by DVFA that all the deficiencies identified had been addressed and corrected. Following this 2003 audit, the DVFA officials agreed to remove this establishment once more from the list of establishments eligible to export to the U.S., as of the start of operations on the day of the audit.

62. AUDITOR SIGNATURE AND DATE

#### united States Department of Agriculture Food Safety and Inspection Service

# Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LODATION	2. AUDITOATE	3 ESTABLISHMENT NO.	TAINAME OF COUNTRY	
Danish Crown-Oksekodsdivisionen,	91 – 10 - 03	62	Denmark	
Aalborg,	5. NAME OF AUDIT	OR(S)	, 6. TYPE OF AUDIT	
Aalborg Ost or Dane Beef, Aalborg Ost	Dr. Oto Urba	n	X ON-SITE AUDIT DOCUM	
Place an X in the Audit Results block to in			<u></u>	IGUA TABN
Part A - Sanitation Standard Operating Procedures	(0000)		rt D - Continued	<del></del>
Basic Requirements	(SSOP) Audit Results		nomic Sampling	Audit Result
7. Written SSOP		33. Scheduled Sample	1 1 1 2 3 3 3 1 1 1 1 1 1 1 1 1 1 1 1 1	0
8. Records documenting implementation.		34. Species Testing		0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue		
Sanitation Standard Operating Procedures (SSOP Ongoing Requirements			Other Requirements	
10. Implementation of SSOP's, including monitoring of impleme		36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's		37. import		
<ol> <li>Corrective action when the SSOPs have failed to prevent d product contamination or adulteration.</li> </ol>	firect	38. Establishment Grounds a	and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Constructi	ion/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light		X
14. Developed and implemented a written HACCP plan .		41. Ventilation		
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac</li> </ol>	ctions.	42. Plumbing and Sewage		-
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>		43. Water Supply		
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>		44. Dressing Rooms/Lavatorie 45. Equipment and Utensils	es	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations		X
18. Monitoring of HACCP plan.		47. Employee Hygiene		
19. Verification and validation of HACCP plan.		48. Condemned Product Control		
20. Corrective action written in HACCP plan.		- Condentitied Foundation		
21. Reassessed adequacy of the HACCP plan.		Part F - Ins	pection Requirements	
22. Records documenting: the written HACCP plan, monitoring o critical control points, dates and times of specific event occu		49. Government Staffing		
Part C - Economic / Wholesomeness	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	50. Daily Inspection Coverage	)	
23. Labeling - Product Standards	0	51. Enforcement		
24. Labeling - Net Weights	0	·		
25. General Labeling	0	52. Humane Handling		
26. Fin. Prod. Standards/Boneless (Defects/AQU/Pork Skins/Mois	sture) O	53. Animal Identification		
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection		
27. Written Procedures		55. Post Mortem Inspection		X
28. Sample Collection/Analysis				, and the second
29. Recoras		Part G - Other Regulat	tory Oversight Requirements	
Salmonella Performance Standards - Basic Require	ements	56. European Community Direc	tives	X
30. Corrective Actions		57. Monthly Review		
81. Reassessment		58.		
2. Writen Assurance		59.		
	<u>-</u>			

#### 60 Observation of the Establishment

DENMARK - Est. 62 1-10-03

- 46/56 (a) The power cord to a compressed-air-powered skinning tool was long enough to contact the floor during the skinning operation, with a potential to cause cross-contamination (it was not observed actually to contact the product). This deficiency was corrected immediately by the establishment officials. (b) The bleeder failed to sterilize his knife, after opening the skin and before opening the major blood vessels, the first time he was observed. This did not meet the requirements of EC Directive 64/433. Danish officials took immediate corrective actions and the deficiency was not repeated.
- 40 Light in the suspect pen was inadequate.
- 55 The conveyor speed of carcasses was slightly faster than that of heads and viscera trays, bringing into some question whether all parts of a carcass could be easily identified, should the need arise. Management stated that they could reliably identify all parts of any carcass during the slaughter process; inspection officials supported this statement, but agreed that the system could be better, and agreed to improve the identification of parts with carcasses.

61. NAME OF AUDITOR

Dr. Oto Urban

16%

62. AUDITOR SIGNATURE AND DATE

MANUAL MANUE MILLER

#### United States Department of Agriculture Food Safety and Inspedion Service

# Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LODATION	2. AUDIT DATE	3.	ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Hjorring Frysehus ApS	01 – 15 - 03		165	Denmark	
Hjorring	5. NAME OF AU	DITOR(S	S)	6. TYPE OF AUDIT	
	Dr. Oto Ur	ban		X ON-SITE AUDIT	DOCUMENT AUDI
Place an X in the Audit Results block to in	idicate noncor	mpliar	nce with require	ments. Use O if not	applicable.
Part A - Sanitation Standard Operating Procedures Basic Requirements	(SSOP) Au			Part D - Continued  Economic Sampling	Audit Results
7. Written SSOP		3:	3. Scheduled Sample		
8. Records documenting implementation.		3-	4. Species Testing		0
9. Signed and dated SSOP, by on-site or overall authority.		3:	5. Residue		0
Sanitation Standard Operating Procedures (SSOP Ongoing Requirements	)		Part I	E - Other Requirements	
10. Implementation of SSOP's, including monitoring of impleme	entation.	36	3. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's	s	37	7. Import		
<ol> <li>Corrective action when the SSOPs have failed to prevent d product contamination or adulteration.</li> </ol>	lirect	38	3. Establishment Ground	ds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39	. Establishment Constr	uction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			). Light		
14. Developed and implemented a written HACCP plan.		41	. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective as	ctions.	42	. Plumbing and Sewage	9	
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	•	43	. Water Supply		
The HACCP plan is signed and dated by the responsible establishment individual.		-	Dressing Rooms/Lava		
Hazard Analysis and Critical Control Point	45. Equipment and Uten				
(HACCP) Systems - Ongoing Requirements		46.	. Sanitary Operations		
18. Monitoring of HACCP plan.		47.	Employee Hygiene		
19. Verification and validation of HACCP plan.		48.	Condemned Product (	Control	
20. Corrective action written in HACCP plan.		-			
21. Reassessed adequacy of the HACCP plan.			Part F -	Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur.		49.	Government Staffing		
Part C - Economic / Wholesomeness		50.	Daily Inspection Cover	rage	
23. Labeling - Product Standards		51.	Enforcement		
24. Labeling - Net Weights			Llumana Handling		
25. General Labeling		52.	Humane Handling		0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moi	sture)	53,	Animal Identification		0
Part D - Sampling Generic <i>E. coli</i> Testing			Ante Mortem Inspection	ח	0
27. Written Procedures	0	55.	Post Mortem Inspection	<u> </u>	0
28. Sample Collection/Analysis	0	1	,		<u> </u>
29. Records	0		Part G - Other Regu	ulatory Oversight Require	ments
Salmonella Performance Standards - Basic Require	ements	56. 	European Community D	rectives	
30. Corrective Actions	0	57.	Monthly Review		
11. Reassessment	0	58.			
2. Written Assurance	0	59.			

60. Observation of the Establishment

DENMARK - Est. 165 1-15-03

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1-15-63

#### United States Department of Agriculture Food Safety and Inspection Service

# Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2 AUDIT DATE	3. ESTABLISHMENTING. 4 NAME OF COUNTRY	
Haderslev Frysehus	01 = 31 - 03	Denmark	
Findlandvej 10	5. NAME OF AU	XTOR(S) 6. TYPE OF AUDIT	
6100 Haderslev	Dr. Oto Ui	ban X ON-SITE AUDIT	DOCUMENT AUDIO
Place an X in the Audit Results block to indi	cate noncoi	npliance with requirements. Use O if not	applicable.
Part A - Sanitation Standard Operating Procedures (Sanitation Basic Requirements	SOP) AL	•	Audit Results
7. Written SSOP		33. Scheduled Sample	0
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementa	ation.	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
<ol> <li>Corrective action when the SSOPs have fated to prevent direct product contamination or adulteration.</li> </ol>	ot	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	0	41. Ventilation	
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective action</li> </ol>	ns. O	42. Plumbing and Sewage	
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	0	43. Water Supply  44. Dressing Roms/Lavatories	
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>	0	45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.	0	47. Employee Hygiene	
19. Verification and validation of HACCP plan.	0	48. Condemned Product Control	
20. Corrective action written in HACCP plan.	0		
21. Reassessed adequacy of the HACCP plan.	0	Part F - Inspection Requirements	
22 Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurre	ne O	49. Government Staffing	77.474.470
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0	52 Humana Handling	
25. General Labeling	0	52. Humane Handling	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moistu	re) O	53. Animal Identification	0
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	0
27. Written Procedures	0	55. Post Mortem Inspection	0
28. Sample Collection/Analysis	0		1
29. Records	0	Part G - Other Regulatory Oversight Require	ments
Salmonella Performance Standards - Basic Requirem	ents	56. European Community Directives	
0. Corrective Actions	0	57. Manthly Review	
1. Reassessment	0	58.	
2 Written Assurance	0	59.	
		-1	

93 Observation of the Establishment

DENMARK - Est. 176 1-31-03

# United States Department of Agriculture Food Safety and Inspection Service

7. ESTABLISHMENT NAMEAND LODATION	2. 4UD.T DATE	3.	ESTABLISHMENT NO	4 NAME OF COUNTRY	
Padborg Frysehus			178	Denmark	
Industrivej 10	5 NAME OF AUDI	TOR(S	<u> </u>	6. TYPE OF AUDIT	
6330 Padborg	Dr. Oto Urb	10.77			
					CUA THEM
Place an X in the Audit Results block to ind	icate noncom	plian	ice with requirer	ments. Use O if not applicab	ole.
Part A - Sanitation Standard Operating Procedures (S Basic Requirements	SSOP) Audit			art D - Continued	Audit
7. Written SSOP	Keuii		EC 3. Scheduled Sample	conomic Sampling	Result
Records documenting implementation.					0
Signed and dated SSOP, by on-site or overall authority.		-	. Species Testing		0
Sanitation Standard Operating Procedures (SSOP)		35	. Residue		0
Ongoing Requirements			Part E	- Other Requirements	
10. Implementation of SSOPs, including monitoring of implement	ation.	36.	Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.		37.	Import		
<ol> <li>Corrective action when the SSOPs have failed to prevent dire product contamination or adulteration.</li> </ol>	ct	38.	Establishment Grounds	and Pest Control	Х
13. Daily records document item 10, 11 and 12 above.	X	39.	Establishment Constru	ction/Maintenance	X
Part B - Hazard Analysis and Critical Control		40.	Light		
Point (HACCP) Systems - Basic Requirements  14. Developed and implemented a written HACCP plan.		41.	Ventilation		
Cortents of the HACCP list the food safety hazards,	0	1	Diversity and O		
critical control points, critical limits, procedures, corrective action		1	Plumbing and Sewage Water Supply		
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	0	40.	Supply		
The HACCP plan is signed and dated by the responsible establishment individual.	0	-	Dressing Rooms/Lavato		
Hazard Analysis and Critical Control Point		40.	Equipment and Otensis		
(HACCP) Systems - Ongoing Requirements		46.	Sanitary Operations		
18. Monitoring of HACCP plan.	0	47.	Employee Hygiene		
19. Verification and validation of HACCP plan.	0	48	Condemned Product Co	ntrol	
20. Corrective action written in HACCP plan.	. 0				
21. Reæsessed adequacy of the HACCP plan.	0	1	Part F - In	spection Requirements	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurre-	ne O	49.	Government Staffing		
Part C - Economic / Wholesomeness	10.00.00	50.	Daily Inspection Coverage	ge	
23. Labeling - Product Standards	0	E4 .			
24. Labeling - Net Weights	0	51.	Enforcement		
25. General Labeling	0	52. I	Humane Handling		0
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moistur	re) O	53. /	Animal Identification		0
Part D - Sampling Generic <i>E. coli</i> Testing		54. A	Ante Mortem Inspection		0
27. Written Procedures					
28. Sample Collection/Analysis	0	55. F	Post Mortem Inspection		0
	- 0	F	Part G - Other Regula	atory Oversight Requirements	
29. Records	0				
Salmonella Performance Standards - Basic Requirem	ents	56. E	uropean Community Dire	ctives	X
0 Corrective Actions	0	57. M	ionthly Review		•
1. Reassessment	0	58.			f 
2 Written Assurance	0	59.			:
				<del></del>	

DENMARK - Est. 178 1-30-03

- 13. The descriptions of both pre-operational and operational findings were inadequate, although corrective actions were adequately described. This was scheduled to be corrected.
- 38/39/56. There were obvious holes under several doors in the cooler area. This deficiency was scheduled for correction by the establishment management. This was in violation of EC Directive 64/433.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

1.300

ix

#### United States Department of Agriculture Food Safety and Inspedion Service

1 ESTABLISHMENT NAME AND LODATION	2 4UDIT DATE	3 ESTABL	ASHMENTINO. 4, MAME OF COUNTRY	
Agri-Norcold A/S, Lilledybet 6,	01-15-03	196	Denmark	
9220 Aalborg Ost	5. NAME OF AUD	TOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urb	va n	X on-site audit	7
				DOCUMENT AUDIO
Place an X in the Audit Results block to Part A - Sanitation Standard Operating Procedu	(000P)	· -	Part D - Continued	
Basic Requirements	res (SSOP) Audi Resul	E .	Economic Sampling	Audit Results
7. Written SSOP		33. Sched	duled Sample	0
8. Records documenting implementation.		34. Specia	es Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Resid	iue	0
Sanitation Standard Operating Procedures (SS Ongoing Requirements	OP)		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of impl	ementation.	36. Expor	t	
11. Maintenance and evaluation of the effectiveness of SSC	DP's.	37. Import	t	
<ol> <li>Corrective action when the SSOPs have failed to preven product contamination or adulteration.</li> </ol>	nt direct X	38. Establ	lishment Grounds and Pest Control	Х
13. Daily records document item 10, 11 and 12 above.	X	39. Establ	lishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Contro		40. Light		
Point (HACCP) Systems - Basic Requirement  14 Developed and implemented a written HACCP plan.		41. Ventila	ation	
15. Cortents of the HACCP list the food safety hazards,	0	42. Plumb	ping and Sewage	
critical control points, critical limits, procedures, corrective.  16. Records documenting implementation and monitoring of	re actions.	43. Water	Supply	
HACCP plan.		44. Dressi	ng Rcoms/Lavatories	X
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>	• O	45. Equipn	nent and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitai	ry Operations	X
18. Monitoring of HACCP plan.	0	47. Employ	yee Hygiene	X
19. Verification and validation of HACCP plan.	0		mned Product Control	
20. Corrective action written in HACCP plan.	0			PROFESSION 1
21. Reassessed adequacy of the HACCP plan.	0		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitor critical control points, dates and times of specific event	ing of the O	49. Govern	nment Staffing	
Part C - Economic / Wholesomeness		50. Daily In	nspection Coverage	
23. Labeling - Product Standards	0	51. Enforce	ement	
24. Labeling - Net Weights	0			
25. General Labeling	0	52. Human	e Handling	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins	/Moisture) O	53. Animal	Identification	0
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mo	ortem Inspection	0
27. Written Procedures	0	55. Post Mo	ortem Inspection	0
28. Sample Collection/Analysis	0			
29. Records	0	Part G	- Other Regulatory Oversight Requirem	ents
Salmonella Performance Standards - Basic Rec		56. Europea	n Community Directives	Х
30. Corrective Actions	0	57. Monthly	Review	
31. Reassessment	0	58.		
32. Writen Assurance	0	59.		
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DENMARK - Est. 196 1-15-03

- 12. The descriptions of the daily sanitation findings and corrective actions were inadequate
- 13. The daily sanitation documentation did not reflect the conditions observed during the audit of this cold store (dirty floor, pieces of broken wood). The establishment management agreed to improve the documentation.
- 38. An open door (possible entrance for rodents) was observed in the shipping area. This was corrected immediately.
- 39/46. Grossly excessive snow and ice were present in one area of the freezer. The establishment scheduled corrective action.
- 44. Housekeeping was very poor in the dressing room: cabinets were covered with dust, and dirty clothes and shoes were stored together with clean work clothes. DVFA ordered prompt corrective actions.
- 47. Employees' helmets in the shipping area were covered with thick dust. The establishment scheduled corrective action.

56/38/39/44/46/47 EC Directive 64/433.

This establishment was issued a Notice of Intent to Delist by the DVFA officials if the deficiencies identified are not corrected within 30 days.

62. AUDITOR SIGNATURE AND DATE

FOR

#### United States Department of Agriculture Food Safet, and Inspedion Service

1 ESTABLISHMENT NAME AND LODATION	2. AUCITICATE	3 ESTABLISHMENTING 4, NAME OF COUNTRY	
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Finlandkaj 2	5. NAME OF AUDIT	OR(S) 6. TYPE OF AUDIT	
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		1 3000	MENT AUDIT
		pliance with requirements. Use O if not applicat	ole.
Part A - Sanitation Standard Operating Procedures (SS Basic Requirements	OP) Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	0
Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation	ion.	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
<ol> <li>Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.</li> </ol>		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	0	41. Ventilation	
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions</li> </ol>	s. O	42. Plumbing and Sewage	
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	0	43. Water Supply	
The HACCP plan is signed and dated by the responsible establishment individual.	0	44. Dressing Rooms/Lavatories  45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.	0		
19. Verification and validation of HACCP plan.	0	47. Employee Hygiene	
		48. Condemned Product Control	
Corrective action written in HACCP plan.     Reassessed adequacy of the HACCP plan.	0	Part F - Inspection Requirements	
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22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrence	es. O	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0	52. Humane Handling	
25. General Labeling	0		0
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisture	) 0	53. Animal Identification	0
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	0
77. Written Procedures	0	55. Post Mortem Inspection	0
8. Sample Collection/Analysis	0		
9. Records	0	Part G - Other Regulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requiremen		56. European Community Directives	
O. Corrective Actions	0	57. Manthly Review	
1. Reassessment	0 5	58.	
2 Written Assurance	0 5	59.	1
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13. The descriptions of pre-operational and operational sanitation findings was not adequately detailed. DVFA ordered corrective action.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND D

2-5-63

#### United States Department of Agriculture Food Safety and Inspection Service

1. ESTABLISHMENT NAME AND LODATION	2. AUG T DA	-TE	B. ESTA	RBUSHMENTING. 4 NAME OF COUNTRY	
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	Dr. Oto			X ON-SITE AUDIT DOCI	UMENT AUD
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7. Written SSOP		- CSuitS	33 50	Economic Sampling heduled Sample	Result
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Signed and dated SSOP, by on-site or overall authority.			ļ	ecies Testing	0
Sanitation Standard Operating Procedures (SSOP)			35. Re		0
Ongoing Requirements				Part E - Other Requirements	
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11. Maintenance and evaluation of the effectiveness of SSOP's.			37. lmp	ort	
<ol> <li>Corrective action when the SSOPs have failed to prevent direction product contamination or adulteration.</li> </ol>	ot		38. Est	ablishment Grounds and Pest Control	
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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Ligh	ıt .	
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<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	(	Ĭ	43. Wate		
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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements				lary Operations	
18. Monitoring of HACCP plan.		_		loyee Hygiene	
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Part C - Economic / Wholesomeness	Two at		in Daily	Inspection Coverage	
23. Labeling - Product Standards			O. Daily		
24. Labeling - Net Weights	0	3	1. Enforc	pement	
25. General Labeling	0	5	2. Huma	ne Handling	0
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moistur			3. Anima	al Identification	0
Part D - Sampling				fortem Inspection	
Generic <i>E. coli</i> Testing					0
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8. Sample Collection/Analysis	0		Part (	G - Other Regulatory Oversight Requirements	
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#### United States Department of Agriculture Food Safety and Inspection Service

26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)  Part D - Sampling Generic E. coli Testing  27. Written Procedures 28. Sample Collection/Analysis 29. Records  Salmonella Performance Standards - Basic Requirements  9. Corrective Actions  1. Resssessment  O 53. Animal Identification  54. Ante Mortem Inspection  C 55. Post Mortem Inspection  O Part G - Other Regulatory Oversight Requirements  56. European Community Directives  7 Monthly Review  1. Resssessment  O 58.	1. ESTABLISMITENT NAME AND LODA TON	2 AUDIT DATE	- 3 ESTABLISHMENTIN	,O 4 NAME OF COUNTRY	
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Part D - Sampling Generic E. coli Testing  54. Ante Mortem Inspection  77. Written Procedures  88. Sample Collection/Analysis  99. Records  90. Part G - Other Regulatory Oversight Requirements  91. Salmonella Performance Standards - Basic Requirements  92. Corrective Actions  93. Corrective Actions  94. Ante Mortem Inspection  95. Post Mortem Inspection  95. Post Mortem Inspection  96. European Community Directives  97. Monthly Review  98. Salmonella Performance Standards - Basic Requirements  98. Salmonella Performance Standards - Basic Requirements  99. Corrective Actions  90. Salmonella Performance Standards - Basic Requirements		<del></del>	52. Humane Handling		0
Generic E. coli Testing  54. Ante Mortem Inspection  C7. Written Procedures  O 55. Post Mortem Inspection  O Part G - Other Regulatory Oversight Requirements  O Salmonella Performance Standards - Basic Requirements  O Corrective Actions  O S8.  O S8.	26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moistur	re) O	53. Animal Identification		0
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9. Corrective Actions O 57. Monthly Review 1. Reassessment O 58.	9. Records		Part G - Other Re	gulatory Oversight Requirements	
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	1. Reassessment	0 5	58.		!
2. Written Assurance O 59.	2 Written Assurance	0 5	59.		

DENMARK - Est. 315 1-28-03

39/56 Rat activity outside the establishment was frequently described in the documentation (there was no sign I of activity in the establishment). Establishment officials stated that the presence of mice was not considered an important problem, only the presence of rats. This misinterpretation of the requirements was corrected immediately.

46/56 Plastic containers designated for edible purposes was used for inedible product (livers contacting the floor), in violation of EC Directive 64/433. This was corrected by the establishment officials.

61. NAME OF AUDITOR Dr. Oto Urban

28 R

62. AUDITOR SIGNATURE AND DATE

### United States Department of Agriculture Food Safet, and Inspection Service

1. ESTABLISHMENT NAME AND LODATION	2. AUDIT DATE	3 ESTABLISHMENTING 4 NAME OF COUNTRY	
Agri-Norcold	01 – 20 - 03	Denmark	
Skivevej 43	5. NAME OF AUDIT	OR(S)   S. TYPE OF AUDIT	
Dk-9500 Hobro	D = 0 = 11.1	V	
	Dr. Oto Urba		CUA T/SM
		liance with requirements. Use O if not applicab	le.
Part A - Sanitation Standard Operating Procedures (SS Basic Requirements	SOP) Audit Results	Part D - Continued Economic Sampling	Audit Result
7. Written SSOP		33. Scheduled Sample	0
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementa	tion.	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
<ol> <li>Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.</li> </ol>	t	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	0	41. Ventilation	
<ol> <li>Cortents of the HACCP list the food safety hazards, oritical control points, critical limits, procedures, corrective action</li> </ol>	ns. O	42. Plumbing and Sewage	
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	0	43. Water Supply	
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>	0	44. Dressing Rooms/Lavatories  45. Equipment and Utensils	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.	0	47. Employee Hygiene	
19. Verification and valdation of HACCP plan.	0	48. Condemned Product Control	
20. Corrective action written in HACCP plan.	0		
21. Reassessed adequacy of the HACCP plan.	0	Part F - Inspection Requirements	
<ol> <li>Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrent</li> </ol>		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0		
25. General Labeling	0	52. Humane Handling	0
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisturi	e) O	53. Animal Identification	0
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	0
27. Written Procedures	0	55. Post Mortem Inspection	0
28. Sample Collection/Analysis	0		
29. Records	0	Part G - Other Regulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requireme	ents	56. European Community Directives	X
80. Corrective Actions		57. Monthly Review	
1. Ressessment	0	58.	;
2. Written Assurance	0	59.	

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- 13 The descriptions of daily sanitation findings did not go into adequate detail. DGAL ordered prompt correction by the establishment officials.
- 39/56 There were obvious holes under the main doors in the shipping area. There was documentation of rodent activity outside the establishment. This did not met the requirements of EC Directive 64/433. This was scheduled for correction by the establishment management.
- 44 Dirty street clothes were mixed with clean work clothes in the dressing room. This was corrected by the establishment officials.

61. NAME OF AUDITOR

1/6

62. AUDITOR SIGNATURE AND DATE

### United States Department of Agriculture Food Safety and Inspection Service

1. ESTABLISHMENT NAME AND LOCATION.	2 AUDITOATE	SLESTABLISHMENTIND 4, NAME OF COUNTRY	
Tulip Food Company 61 =		4533 Denmark	
Fedtsmeltiriet 8900 Randers	5. NAME OF AUDI	TOR(8) 8 TYPE OF AUDIT	
6900 Kanders	Dr. Oto Urb	an X ON-SITE AUDIT DOGU	JMENT AUDI
Place an X in the Audit Results block to ind	icate noncom	pliance with requirements. Use O if not applicat	
Part A - Sanitation Standard Operating Procedures (S Basic Requirements	SOP) Audit	Part D - Continued	Audit Result
7. Written SSOP		33. Scheduled Sample	
Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	0
10. Implementation of SSOP's, including monitoring of implementation	ation.	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. import	
<ol> <li>Corrective action when the SSOPs have falled to prevent direct product contamination or adulteration.</li> </ol>	ct	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control		40. Light	
Point (HACCP) Systems - Basic Requirements  14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Cortents of the HACCP list the food safety hazards	0	42. Plumbing and Sewage	
critical control points, critical limits, procedures, corrective action.  16. Records documenting implementation and monitoring of the	ns. O	43. Water Supply	
HACCP plan.  17. The HACCP plan is signed and dated by the responsible	0	44. Dressing Rooms/Lavatories	
establishment individual.		45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.	0	47. Employee Hygiene	
19. Verification and valdation of HACCP plan.	0	48. Condemned Product Control	
20. Corrective action written in HACCP plan.	0	46. Condemical roduct control	
21. Reassessed adequacy of the HACCP plan.	0	Part F - Inspection Requirements	
<ol> <li>Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrent</li> </ol>	ne O	49. Government Staffing	
Part C - Economic / Wholesomeness	10/08.05.050	50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0		
25. General Labeling	0	52. Humane Handling	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moistur	-e) O	53. Animal Identification	0
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	0
7. Written Procedures	0	55. Post Mortem Inspection	0
8. Sample Collection/Analysis	0		
9. Records	0	Part G - Other Regulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requireme	ents	56. European Community Directives	
C. Corrective Actions	0	57. Manthiy Review	
. Reassessment	0	58.	
2. Writen Assurance	0	59.	<del></del>
SIS- 5000 6 (0404/2002)			<del> </del>

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13 Preventive measures were not included in the daily SSOP records. This was scheduled for correction by the establishment officials.

61. NAME OF AUDITOR

Dr. Ote Urban

ZZK

62. AUDITOR SIGNATURE AND DATE

1.2203

### Ministeriet for Fødevarer, Landbrug og Fiskeri Fødevaredirektoratet

Danish Veterinary and Food Administration



United States Department of Agriculture Food Safety and Inspection Service Washington, D.C. 20250

20250 USA att.: Sally Stratmoen, Acting Director

International Equivalence Staff
Office of International Affairs

Date: 1 August 2003

Our ref.: HP

File: 2002-20-7515-00017

Please note when replying

Sent by fax 202-690-4040 3 pages incl. this page.

Re.: Comments on draft audit report.

This is in response to letter of May 19, 2003 from FSIS, enclosed the draft audit report for the on-site audit of Denmarks meat inspection system, conducted by FSIS from January 6, 2003 through February 5, 2003.

By the letter Denmark was ir vited to provide comments regarding the information in the report within 60 days of the receipt of the letter. The Danish Veterinary and Food Administration (DVFA) hereby wish to forward the following comments:

Page 5, section 2:

"... the following sites were visived:... four swine slaughter establishments..."

Comment: two cattle and two swine slaughter establishments were visited.

Page 7, section 5:

"The last two audits of Denmarks inspection system have shown serious problems"

Comment: DVFA is of the opinion that it is concluded in the audit reports for the last two years, that Denmark has a well functioning inspection system in compliance with the USA requirements.

BW 8/1/02

Page 8, section 6.2.1:

"Within the Food Control Department of each RVFCA were the Chief Veterinarians, who served as field supervisors over the resident veterinarians and inspectors within one or more certified establishments"

Comment: DVFA agree that the Chief Veterinarians serves as field supervisors over the resident veterinarians, meaning that they are leaders for the veterinarians. However the monthly reviews are not in all cases carried out by Chief Veterinarians. The reviews can also be carried out by other specialised auditors in the RVFCA's.

Page 8, section 6.2.2:

"Two establishments required a 30-day letter from the CCA"

Comment: Please see the below mentioned comments on section 7.

Page 8, section 6.2.3:

"Supervision of inspectors in the certified establishments needs to be improved"

Comment: DVFA has revised the instructions to the RVFCAs on how to carry out the monthly reviews, with a view to improve the follow-up procedures in connection with findings of deficiencies in the certified establishments.

Please also refer to letter from DVFA of 19 June 2003 describing the plans for a new audit unit in DVFA.

Page 9, section 6.2.4:

"In one establishment, zero tolerance for fecal contamination was not enforced"

Comment: DVFA agree that a deficiency concerning fecal contamination was found in one establishment. This, however, does not mean that the zero tolerance for fecal contamination was not enforced. The zero tolerance is enforced in all establishments.

Page 10, section 7:

"Two establishments received a "30-day letters" (notification in writing that corrective actions must be implemented within 30 days)"

#### Comment:

The follow-up on the 2 companies which received a Notice of Intent to Delist, has been as follows:

Est. No. 196, Agri-Norcold, Aalborg, date of audit 15 January 2003:

- The audit findings were informed to the company by letter of 28 January 2003 from RVFCA-Aalborg. The Company was ordered to write a response letter before 10 February 2003, including an action plan for correcting the deficiencies, specially the SSOP and the HACCP programme,
- By letter of 6 February 2003 the company responded as requested
- RVFCA- Aalborg carried out a new audit on 14 February 2003. It was concluded, that the company had sufficiently corrected the deficiencies, and had improved the SSOP and FIACCP programmes sufficiently.

Est. No. 13, Danish Crown, Hjørring, date of audit 16 January 2003:

- The audit findings were informed to the company by letter of 20 January 2003 from RVFCA-Aalborg. The Company was ordered to write a response letter before 6 February 2003, including an action plan for correcting the deficiencies, specially the SSOP programme and the own-check programme, as regards maintenance.
- By letter of 30 January 2003 the company responded as requested
- RVFCA- Aalborg carried out a new audit on 13 February 2003. It was concluded, that the company had sufficiently corrected the deficiencies, and had sufficiently improved the SSOP and own-check programme.

Page 15, section 13.2, subsection 1:

"Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and the DVFA analyzes the sample"

Comment: Salmonella verification samples are taken by the RVFCAs once every week in each slaughter establishment, as a routine. These samples are analysed at the RVFCA laboratories.

Yours Sincerely

Dr. Birgitte Povlsen
Senior Veterinary Officer
Head of Import-Export Division
Food Department